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09/728,553	12/02/2000	Peter M. Bonutti	BON-4363	5055

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EXAMINER

LEWIS, AARON J

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,553

Applicant(s)

BONUTTI, PETER M.

Examiner

AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/29/2003 (ELECTION).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-242 is/are pending in the application.
- 4a) Of the above claim(s) 1-99, 107-115, 139-168, 195-198 and 218-222 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 181-194, 213-217, 223 and 224 is/are allowed.
- 6) ☒ Claim(s) 100-106, 169, 170, 178, 199, 202-204, 206, 208, 211, 225-230, 233 and 234 is/are rejected.
- 7) ☒ Claim(s) 171-177, 179, 180, 200, 201, 205, 207, 209, 210, 212, 231, 232 and 235-242 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of claims 100-106, 169-194, 223-242 in Paper No. 05 is acknowledged. The traversal is on the ground(s) that a search and examination of the entire application can be made without serious burden. This is not found persuasive because there are at least four distinct inventions defined by all of the claims in the instant application and each with a separate utility and separate classification; accordingly, restriction for examination purposes is deemed to be proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 100-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson ('362).

As to claim 100, Anderson discloses a method of treating a patient, said method comprising moving a leading end portion (27) of a member (23) disposed in a patient's body (fig.5) relative to body tissue, said step of moving a leading end portion of a member relative to body tissue includes attracting the leading end portion of the member with a magnetic field (41) emanating from a location outside of the patient's body (fig.5).

As to claim 101, Anderson discloses the step of attracting a leading end portion (27) of the member (23) includes inducing the leading end portion of the member to move from a position offset to one side of an opening into the opening (col.6, lines 27-40).

As to claims 102 and 103, Anderson as discussed above with respect to claim 101, also discloses the further step of applying force against a trailing end portion of the member (23) to move the member relative to body tissue, and steering (by deflecting the leading end portion as illustrated in fig.5) the leading end portion of the member relative to the body tissue under the influence of the magnetic field emanating from a location outside of the patient's body as the member moves relative to the body tissue under the influence of the force applied against the trailing end portion of the member. The steps of sliding and inserting member (23) as expressly disclosed in Anderson (col.6, lines 27-40) inherently include manual manipulation of member (23) at a portion thereof which is readable upon a trailing end portion in an effort to slide and/or insert member (23) further into a patient's trachea.

As to claim 104, while Anderson does not expressly disclose a step of moving the magnetic field relative to a patient's body, it is submitted that a step of moving the field (41) is inherent in the method of intubation in Anderson because as the leading end portion (27,37) is inserted further into a patient's throat, the external magnetic field must also be moved downwards in order to maintain control over the leading end portion during guiding of the leading end portion through a patient's larynx and into a patient's trachea.

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As to claim 105, Anderson as discussed above with respect to claims 102-103 also discloses the step of applying force against a first portion (i.e. inherently include manual manipulation of member (23) at a portion thereof outside a patient's mouth which is readable upon a first portion in an effort to slide and/or insert member (23) further into a patient's trachea), and changing a path of movement of the member relative to the body tissue (fig.5) while continuing to move the member relative to the body tissue under the influence of force applied (i.e. manual manipulation) to the first portion of the member, said step of changing the path of movement of the member relative to the body tissue includes attracting a second portion (#39,37 of fig.5) of the member with a magnetic field (41) having a source disposed outside of the patient's body.

As to claim 106, while Anderson does not expressly disclose a step of moving the magnetic field relative to a patient's body, it is submitted that a step of moving the field (41) is inherent in the method of intubation in Anderson because as the leading end portion (27,37) is inserted further into a patient's throat, the external magnetic field must also be moved downwards in order to maintain control over the leading end portion during guiding of the leading end portion through a patient's larynx and into a patient's trachea.

4. Claims 169,170,178,202-204,208,211 are rejected under 35 U.S.C. 102(b) as being anticipated by White ('636).

As to claim 169, White discloses a method of tracheal intubation, said method comprising the steps of positioning a plurality of detectors (col.9, lines 17-21) in an array adjacent to an outer surface of a patient's neck, moving a tracheal tube (18) relative to

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the patient's respiratory system along an insertion path which extends from the patient's pharynx, through the patient's larynx and into the patient's trachea, emitting (32) an output at a leading end position (figs. 1, 11, 18) of the tracheal tube as the tracheal tube moves along the insertion path, detecting (figs. 15, 17) the output emitted at a leading end portion of the tracheal tube with detectors of a plurality of detectors (col. 9, lines 17-21), and determining the position of the leading end portion of the tracheal tube along the insertion path as a function of the relationship of the emitted output detected by one detector of the plurality of detectors to the emitted output detected by another detector of the plurality of detectors.

As to claim 170, White discloses the step of emitting an output at a leading end portion of the tracheal tube (18) includes emitting a magnetic field from a magnet (20) connected with the leading end portion of the tracheal tube.

As to claim 178, White discloses the step of positioning a plurality of detectors in an array adjacent to an outer surface of the patient's neck (col. 9, lines 17-21). This array is disclosed as being arranged over the thyroid cartilage of the patient; accordingly, (inasmuch as the thyroid cartilage is consistent with the Adam's apple) this array of detectors inherently extends at least part way around the patient's Adam's apple.

As to claim 202, White discloses an apparatus for use in tracheal intubation of a patient, said apparatus comprising a tracheal tube which is moveable along an insertion path into a patient's trachea, an emitter (20) which provides an output, and a detector (22) which responds to the output from said emitter, a first one of said emitter (20) and said detector being connected with said tracheal tube (#18 of fig. 7) for movement

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therewith along the inserting path, a second one of said emitter and said detector (22) being disposed adjacent to an outer surface of the patient's neck (figs.11,14-18) during movement of said tracheal tube along the insertion path.

As to claim 203, White discloses the emitter (20) includes a magnet that emits a magnetic field and said detector (22) includes a device that responds to a magnetic field.

As to claim 204, White discloses the emitter to be connected with a leading end portion of said tracheal tube (18) for movement along the insertion path.

As to claim 208, White discloses an apparatus for use in tracheal intubation of a patient, said apparatus comprising a tracheal tube (18) which is movable along an insertion path into a patient's trachea, an emitter (20) connected with a leading end portion of said tracheal tube, said emitter being effective to provide an output during movement of said tracheal tube along the insertion path, and a plurality of detectors in an array adjacent to the patient's Adam's apple (col.9, lines 17-21), each detector of said plurality of detectors being responsive to the output from said emitter and means connected with said plurality of detectors for determining the position of the leading end portion of said tracheal tube along the insertion path as a function of outputs from said plurality of detectors during movement of said tracheal tube along the insertion path (figs.11,14-18).

As to claim 211, White discloses the emitter to include a magnet (20) which emits a magnetic field, each of said detectors (22) of said plurality of detectors being responsive to the magnetic field emitted by said magnet.

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5. Claim 199 is rejected under 35 U.S.C. 102(b) as being anticipated by Berci ('153).

As to claim 199, Berci discloses an apparatus for use in tracheal intubation, said apparatus comprising a tracheal tube (figs.3,4), sensor means (22) connected with said tracheal tube for determining the position of the leading end portion of said tracheal tube during movement of said tracheal tube along an insertion path which extends from a patient's pharynx, through the patient's larynx and into the patient's trachea (fig.4), and steering means (54) connected with a leading end portion of said tracheal tube for applying force against the leading end portion (col.6, lines 7-16) of said tracheal tube (fig.3) during movement of said tracheal tube along the insertion path.

6. Claims 225-230,233,234 are rejected under 35 U.S.C. 102(b) as being anticipated by Hawk ('872).

As to claim 225, Hawk discloses a method of treating a patient, said method comprising the steps of locating a positioning apparatus (10,60) relative to a portion of the patient's body (i.e. mouth/throat) by engaging the patient's body with the positioning apparatus, determining a position to which an elongated member (i.e. endotracheal tube) is to be moved relative to the positioning apparatus (col.4, lines 59-61), moving the elongated member into the patient's body while the positioning apparatus is in engagement with the patient's body (col.4, lines 66-67), interrupting movement of the elongated member into the patient's body when the elongated member has moved to the previously determined position relative to the positioning apparatus (i.e. after positioning the endotracheal tube within a patient's trachea), and performing a

procedure (e.g. ventilating the patient via the endotracheal tube) in the patient's body while the elongated member is in the previously determined position relative to the patient's body.

As to claim 226, Hawk discloses the step of moving an elongated member into a patient's body includes moving at least a portion of the elongated member through a portion of the positioning apparatus (fig.5 and 10a-d) which is aligned with an opening in the patient's body (col.4, lines 31-33).

As to claim 227, Hawk discloses varying the spatial relationship between first (14) and second (15) portions of the positioning apparatus, said step of determining a position to which the elongated member is to be moved relative to the patient's body includes determining the position as a function of the spatial relationship between the first and second portions of the positioning apparatus (col.4, lines 54-65) after the positioning apparatus has been located relative to the patient's body (col.4, lines 59-61) and when the positioning apparatus is disposed in engagement with the patient's body.

As to claim 228, Hawk discloses disengaging the positioning apparatus from the elongated member prior to performance of said step of performing a procedure in the patient's body (col.4, lines 43-44), said step of disengaging the positioning apparatus from the elongated member is performed with a portion of the elongated member in the patient's body.

As to claim 229, Hawk discloses sliding the elongated member along a guide surface (10a-d) connected with the positioning apparatus, said method further including separating the positioning apparatus from the elongated member while the elongated

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member extends in to the patient's body (col.4, lines 43-44), and, thereafter, performing said procedure (i.e. ventilating the patient) in the patient's body.

As to claim 230, Hawk (col.4, lines 31-33) discloses engaging spaced apart locations (mouth opening and throat) on the patient's body with the positioning apparatus (10,60).

As to claim 233, the insertion of an endotracheal tube using the positioning apparatus of Hawk inherently includes the steps of manually manipulating any portion of the endotracheal tube into a patient's trachea by manually manipulating the tracheal tube around any obstructions. Such manual manipulation would include applying force to portions of the endotracheal tube in order to accomplish proper intubation.

As to claim 234, Hawk discloses the step of transmitting an image from a leading end portion of the elongated member (col.5, lines 11-12) to a location outside of the patient to facilitate visualization of tissue disposed in the patient's body adjacent to the leading end portion of the elongated member.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 206 is rejected under 35 U.S.C. 103(a) as being unpatentable over White ('636).

As to claim 206, while White does not expressly disclose sensor (22) to be a Hall effect device for measuring magnetic field generated by magnet (20), it is submitted that

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the detector circuit illustrated in fig.6 is exemplary of a circuit which is typically employed to demonstrate the Hall effect and is therefore, readable upon a Hall effect device. That is, the magnetic field of magnet (20) would be imposed onto the current within the circuit of fig.6 in an effort to demonstrate whether the current within the circuit of fig.6 is due to electrons or holes.

Allowable Subject Matter

9. Claims 171-177,179,180,200,201,205,207,209,210,212,231,232,235-242 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 181-194,213-217,223-224 are allowed.

Conclusion

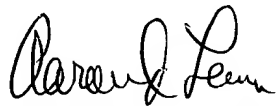
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant methods of treating patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
November 16, 2003